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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	02/09/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	09/743,577	SCHLACHTER, HERBERT	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-13,17-19 and 22-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-13, 17-19 and 22-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt for Request for Continued Examination is filed on 12/29/06 is acknowledged. Claims **2-13, 17-19 and 22-40** are pending in this application. Claims 1, 14-16, and 20-21 stand cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 40 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating skin irritations, sun burn, cellulites, wrinkles, acne, neurodermatitis, ozone damage, burns, caustic burns, thickening, edemas, hematomas, hemorrhoids, does not reasonably provide enablement for treating skin cancer and herpes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement is considered in the view of the Wands factors (MPEP 2164.01 (a)). These include the nature of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, and state of the prior art. All of the Wands factors have been considered with the regard to the instant claims, with the most relevant discussed below.

Nature of the Invention: Rejected claim 40 is drawn to a method of treating skin irritations, sun burn, cellulites, wrinkles, acne, neurodermatitis, ozone damage, burns, caustic burns, thickening, edemas, herpes, hematomas, hemorrhoids, and skin cancer with a topical

composition containing 1) an alkali or alkaline earth metal salts or other minerals, 2) at least one amino acid, 3) zinc oxide and an inorganic peroxide, 4) and a secondary plant substance.

Breath of the claims: The complex nature of the claims is greatly exacerbated by the breath of the claims. The invention encompasses treating a *divergent* skin disorders ranging from minor skin irritations to skin cancer, which are caused by unrelated factors, with one topical composition.

Guidance of the Specification: The guidance by the specification discloses that the individual "recipe" of the composition provides for a certain treatment. Thus, depending on the active agents added, the desired disorder will be treated. However, rejected claim 40 recites a generic composition of four broad elements to treat all the divergent skin diseases listed, whereas the specification states that the treatment depends on the recipe. Thus, the specification is limited, if not lacking, in guidance on the "recipe" that actually treats the skin disorder of choice. For instance, the specification does not provide one reasonable guidance on how to treat skin cancer, herpes, arthrosis, or rheumatism with the instant composition.

Working Examples: All of the working examples provided by the specification are directed towards the improvement of wrinkles and microcirculation. The examples do not speak on the treatment of other divergent skin disorders such as skin cancer, with the generic composition.

The State of the Art: The prior art teaches various drugs to treat the divergent diseases listed in claim 40. For instance, the prior art teaches the use of cytoxic drugs, i.e. neoplastic agents, anticancer agents, etc., to treat skin cancer. Further, the prior teaches the use of antivirals to treat herpes, however the instant invention claims to treat herpes without the requisite antiviral

agents. Thus, it can be seen that the composition that is directed to treating these disorders does not have the requisite drug to treat the skin disorder.

Undue Experimentation: The instant invention requires undue experimentation to find the appropriate "recipe" to treat the appropriate disease. Firstly, there is a multitude of possible combinations of the optional ingredients in the specification. Thus, a skilled artisan would first need to ascertain the appropriate combination of components in the exahasitive list in the specification, then a skilled artisan would need to test the each possible combination, and the skin disease and ascertain which skin disorder, the combination treats. Further, a skilled artisan would have to experiment to find to appropriate and effective dosage, if any, to provide an effective treatment. Thus, the instant invention requires undue experimentation for a skilled artisan to practice the invention.

Response to Arguments

Applicant argues that Watzl et al disclose the use of the instantly claimed secondary plant substances (SPS) have anticarcinogenic effects to treat skin cancer.

Applicant's arguments filed 12/29/05 have been fully considered but they are not persuasive. Firstly, the examiner notes that applicant has not provided the an IDS citing Waltz et al, nor has applicant provided page 250 in which the Table has been removed from. The examiner only notes that applicant has "cut and paste" the Table on the last page of the argument. Moreover, applicant has not certified the English translation. Therefore, the rejection is maintained until the applicant provides the examiner with a copy of page 250 in which the Table was obtained from and applicant certifies the translation.

Moreover, the examiner points out the instant claims are not directed to any specific weight percent of the plant substances. Since applicant has not provided the pertinent pages of Waltz applicant relies on to demonstrate enablement, the examiner cannot determine if Waltz teaches a concentration the plant substances that needs to be utilized to provide the anticarcinogenic effect. Thus, applicant may not be enabled to treat skin cancer with any concentration. For instance, applicant may not be enabled to treat skin cancer with a composition that may contain only trace amount of the plant substance. The examiner points out that it would be an undue burden for a skilled artisan to determine the concentration of the plant substance required to provide an effect such as treating skin cancer. The use of plant substances to treat skin cancer is not conventional and routine; thus a skilled artisan would have experiment extensively to find the appropriate dosage amount.

Response to Arguments to Prior Art

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. However, since the examiner has retained Oliver et al, the examiner will address applicant arguments pertaining to Oliver, Horrobin, and Burke.

Applicant argues Oliver does not teach a secondary plant substance and plant extract do not automatically contain secondary plant substances. The examiner respectfully disagrees. The instant claims recite terpenes in the Markush group. The examiner points out that tea tree oil necessarily contains terpenes.

Applicant argues that Oliver does not teach organic peroxides. The examiner respectfully disagrees. Oliver teaches hydrogen peroxide, which is an inorganic peroxide.

Applicant argues that Oliver is directed to a composition comprising only natural ingredients without the use of salts. Firstly, the examiner points out that the claims are directed to a salt or mineral. The examiner points out that Oliver teaches the golden seal extract itself includes calcium, chlorine, iron, manganese, phosphorus, potassium, etc. Further, Oliver teaches calamine, which comprises zinc oxide and 0.5% ferric oxide.

Applicant argues that Oliver does not teach the use of zinc oxide in combination with an inorganic peroxide. The examiner points out that the formulation comprises 18% zinc oxide and 5% peroxide. Oliver teaches hydrogen peroxide as the peroxide component but may also be selected from may also be selected from benzoyl peroxide, acetyl peroxide, t-butyl peroxide, para chlorobenzoyl peroxide, and methyl ethyl ketone peroxide. Thus, Oliver prefers hydrogen peroxide, but also teaches other peroxides may be used. The fact that the other peroxides suggested are organic peroxides is not a teaching away from hydrogen peroxide. Oliver clearly suggests the use of hydrogen peroxide and prefers its use.

Applicant argues Horrobin does not teach zinc oxide, an inorganic peroxide, and an amino acid. The examiner points out that the instant claims are rejected under obviousness. The test for obviousness is not whether the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In instant case, the examiner relies on Horrobin to cure the deficiencies of Oliver. Horrobin is specifically relied on to teach the use of polyunsaturated fatty acids and amino acids. Further, it is noted applicant attacks the references individually whereas the reject is based on a combination of references. Applicant has not addressed the examiner's motivation.

Applicant argues Burke is directed to a cleanser. Applicant argues that Burke does not teach an amino acid, at least one secondary plant substance, zinc oxide, and a inorganic peroxide. Again, the examiner points out that Burke is not relied to teach a plant substance, zinc oxide, an inorganic peroxide, or an amino acid since the combination of Oliver and EP '812 or Horrobin, respectively, is not deficient in this sense. Burke is only relied upon to teach the functional equivalency of the claimed peroxides and Oliver's hydrogen peroxide. Applicant has not addressed the examiner's motivation or provided any unexpected results to overcome this rejection.

With regard to the fact that Burke teaches a cleanser and is non-analogous, the examiner it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In instant case, Oliver teaches the use of hydrogen peroxide to treat infection of the skin. The examiner points out that Burke teaches hydrogen peroxide, zinc peroxide, sodium peroxide all function to disinfect the skin. Thus, both references are in the same field of endeavor and Burke teaches the same pertinent problem discussed by Oliver.

Response to Amendment

The Declaration under 37 CFR 1.132 filed 5/26/06 is insufficient to overcome the rejection of claims because:

Firstly, the declaration attempts to show that the combination of zinc oxide and a inorganic peroxide provide an increased anti-inflammatory effect. However, the examiner points

out that this is ineffective since Oliver teaches the combination of zinc oxide and a inorganic peroxide to treat skin orders such as acne, rashes, etc. Thus, demonstrating the unexpected of the a combination of zinc oxide and an inorganic peroxide is ineffective since the prior art teaches this combination. The examiner further points out that the "[m]ere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention." In re Baxter Travenol Labs, 952 F.2d 388,392, 21 USPQ2d 1281, 1285 (Fed. Cir. 1991). Further, the examiner notes that applicant broadly claims a secondary plant substances, salts or minerals, and amino acids whereas the "unexpected results" utilize a specific combination comprising a specific salt, a specific amino acid, and a specific unsaturated fatty acid. *If* applicant can show unexpectedness, the claims must be commensurate in scope since a single species does not demonstrate the unexpectedness of the entire claimed genus. Thus, the Rule 132 declaration is ineffective.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 5-11, 17-19, 26-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oliver (5,869,062) in view of EP 0281812.

Oliver teaches a skin treatment composition for skin-related problems especially acne and blemishes. See column 1, lines 4-11 and claims. The composition comprises 8-20% calamine (zinc oxide with 0.5% ferric oxide); 0.05-3% antioxidant; and 0.25-4% of an anti-bacterial. The composition further includes one or more astringents and a peroxide component such as hydrogen peroxide. See column 1, lines 35-50 and column 3, lines 9-10. Oliver teaches calamine reduces inflammation, redness and itching, as well as for drying out excess oils and fluids. See column 2, lines 14-20. The second critical component is at least one anti-oxidant, which prevents free radical damage. Such as vitamin C (ascorbic acid between 0.45 and 2 weight percent), vitamin E (between 0.08 and 1.0 weight percent), and beta-carotene (vitamin A). See column 2, lines 20-30. The naturally occurring anti-bacterial includes 0.35-0.95% golden seal extract, 1-3% tea tree oil (contains terpenes), echinacea, garlic, and red clover. Oliver teaches the additional use of an astringent such as witch hazel and alpha hydroxy acids. The preferred astringent is witch hazel and the preferred range of the astringent is in an amount between about 1 and 12 %. See column 2, lines 57-65. The golden seal extract itself includes albumin, berberine, biotin, calcium, candine, chlorine, choline, chologenic acid, fat, hydrastine, inositol, iron, lignini manganese, volatile and essential oils, PABA, phosphorus, potassium, resin, starch, sugar, B complex and vitamins and acts to fight infections. See column 2, lines 40-47. Oliver teaches the use of a peroxide in an amount between about 3 and 8%, which to help treat any infection. Zinc

oxide in the amount of 8-20% also is taught as an additional base. Aloe vera may be included in the amount of 0.01-0.05% for sever skin problems.

Oliver teaches a composition water, 20% glycerin (humectant), 18% calamine (contains zinc oxide with 0.5%), 18% zinc oxide, 5% witch hazel, 0.88% ascorbic acid, 5% EDTH, 5% peroxide, 2% golden seal, 0.70% tea tree oil, and 0.16% vitamin E.

Oliver does not teach an amino acid in the composition.

EP 0281812 teaches a composition for the treatment of acne comprising a keratolytic agent, an astringent such as zinc oxide, and an anti-inflammatory agent such as amino acids. EP '812 teaches amino acids are know to have anti-inflammatory activity and include cysteine, L-tryptophan, valine, alanine, glycine, glutamine, and aspartic acid in 2-30%. See column 5, lines 45-50. In the preferred embodiment, the acne treating composition comprising salicylic acid, zinc oxide, and cysteine. See column 6, lines 30-34.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Oliver and EP '812. One would have been motivated to further utilize amino acids in Oliver's composition to provide an additive anti-inflammatory activity. Further, a skilled artisan would have been motivated to combine the teaching with a reasonable expectation of success since both references teach the treatment of acne. Therefore, "it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Claims 2-11, 13, 17-19, 22-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oliver (5,869,062) in view of Horrobin (5,145,686).

Oliver teaches a skin treatment composition for skin-related rashes, skin bites, razor irritation, chicken pox, athlete's foot, general itching, and acne. See column 1, lines 4-11 and claims. The composition comprises 8-20% calamine (zinc oxide with 0.5% ferric oxide); 0.05-3% antioxidant; and 0.25-4% of an anti-bacterial. The composition further includes one or more astringents and a peroxide component such as hydrogen peroxide. See column 1, lines 35-50 and column 3, lines 9-10. Oliver teaches calamine reduces inflammation, redness and itching, as well as for drying out excess oils and fluids. See column 2, lines 14-20. The second critical component is at least one anti-oxidant, which prevents free radical damage. Such as vitamin C (ascorbic acid between 0.45 and 2 weight percent), vitamin E (between 0.08 and 1.0 weight percent), and beta-carotene (vitamin A). See column 2, lines 20-30. The naturally occurring anti-bacterial includes 0.35-0.95% golden seal extract, 1-3% tea tree oil (contains terpenes), echinacea, garlic, and red clover. Oliver teaches the additional use of an astringent such as witch hazel and alpha hydroxy acids. The preferred astringent is witch hazel and the preferred range of the astringent is in an amount between about 1 and 12 %. See column 2, lines 57-65. The golden seal extract itself includes albumin, berberine, biotin, calcium, candine, chlorine, choline, chologenic acid, fat, hydrastine, inositol, iron, lignini manganese, volatile and essential oils, PABA, phosphorus, potassium, resin, starch, sugar, B complex and vitamins and acts to fight infections. See column 2, lines 40-47. Oliver teaches the use of a peroxide in an amount between about 3 and 8%, which to help treat any infection. Zinc oxide in the amount of 8-20% also is

taught as an additional base. Aloe vera may be included in the amount of 0.01-0.05% for sever skin problems.

Oliver teaches a composition water, 20% glycerin (humectant), 18% calamine (contains zinc oxide with 0.5%), 18% zinc oxide, 5% witch hazel, 0.88% ascorbic acid, 5% EDTH, 5% peroxide, 2% golden seal, 0.70% tea tree oil, and 0.16% vitamin E.

Oliver does not teach an amino acid in the composition. Further, Oliver does not teach a polyunsaturated fatty acid.

Horrobin et al teach a topical pharmaceutical composition containing for the treatment of lesions causes by allergic reactions, insect bites, wounds, and the composition provides a soothing effect. See column 4, lines 10-25. The composition comprises lysine in the amount of 0.01-20% for the treatment of lesions (column 1, lines 53-55; zinc salts 0.01-10% for the bioconversion of linoleic acid and its own healing properties (column 5, lines 3-14); rutin which comprises bioflavonoids for blocking prostaglandin synthesis; and linoleic acid from vegetable oils for treating skin inflammation (column 2, lines 30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Oliver and Horrobin et al and further utilize lysine and polyunsaturated fatty acids in Oliver's composition. One would have been motivated to do so since Horrobin teaches lysine treats lesions of the skin and polyunsaturated fatty acids provide an anti-inflammatory effect. Therefore, a skilled artisan would have been motivated to additionally add a polyunsaturated fatty acid for its additive effect of treating skin inflammation and utilize lysine in treating skin lesions caused by the allergic reactions, bites, and acne. Further, a skilled artisan would have been motivated to combine the teaching with a reasonable expectation of

success since both references teach the treatment of skin rashes and inflammation and to provide a soothing effect. Therefore, "it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Murad (5,962,517) in view of Oliver (5,869,062) in view of Horrobin (5,145,686) or EP 0281812 respectively, in further view of Burke et al (5,693,318).

The disclosure of Oliver, Horrobin, and EP'812 have been set forth above. As noted in the discussion of Oliver, Oliver teaches the use of peroxide such as hydrogen peroxide in the composition to treat infection. The combined references do not teach the instant peroxides claimed.

Burke teaches keratolytic agent such as salicylic acid and peroxide compounds which acts as an antiseptic for disinfecting the skin. See abstract and column 1, lines 15-30. Burke teaches peroxides useful include hydrogen peroxide, zinc peroxide, sodium peroxide. The peroxides are used at a preferred level of 0.5 to 5% by weight, a more preferred level of 0.5 to 3% by weight and a most preferred level of 1 to 2% by weight. See column 5, lines 35-50.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and substitute hydrogen peroxide with the instantly claimed peroxides. One would have been motivated to do so with the reasonable expectation of similar results since Burke teaches hydrogen peroxide and the instantly

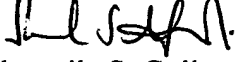
claimed peroxides all function as disinfectants and may be used topically to treat the skin. Therefore, it prima facie obvious to substitute one equivalent component for another equivalent with the expectation of similar results since the art clearly establishes functional equivalency, i.e. the pharmacological property of acting as a disinfectant when topically applied.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Sharmila S. Gollamudi
Examiner
Art Unit 1616